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EXAMINER	
WATTS, JENNA A	

ART UNIT	PAPER NUMBER
1781	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patents-US-NY@novozymes.com

Office Action Summary	Application No.	Applicant(s)	
	10/550,996	ZHOU, ZHIWEI	
	Examiner	Art Unit	
	Jenna A. Watts	1781	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20100401*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kogya (CN 87103320 A) in view of Kuntz (Food Product Design article, 1996), in view of Tsai (U.S. Patent No. 4639375), and further in view of Agbo et al. (U.S. Patent No. 5,445,836).

4. Regarding Claims 7-12, Kogya teaches reducing storage sediment/haze formation in a packaged tea extract (Page 1, Paragraph 1), by taking tea extract and combining it with a particular amount of a pectinase enzyme (Page 2, Paragraph 7). Kogya also teaches preparing a control tea product without enzyme added (Page 2,

Paragraph 7). The combination of the tea extract and pectinase is then mixed and allowed to stand (Page 2, Paragraph 7). The sediment is then separated by centrifugation and the amount of sediment measured (Page 2, Paragraph 7). The resulting tea drink is then packaged by loading the tea extract into 180ml flasks and is then sterilized (Page 3, Paragraph 6). The filled flasks or bottles are subsequently stored at various temperatures, including room temperature, until any sediment is formed (Page 3, Paragraph 6). Kogya teaches that the drink produced by the method of the invention did not give rise to sediment/haze even after 6 months of storage (Page 3, Paragraph 6), thus the reduction of storage induced sediment/haze formation can be seen as 100%, as compared to the untreated tea product. The storage induced sediment/haze formation would also then be reduced by at least 10%, and at least 50%, 75%, 90%, 95%, 99%, as compared to an untreated tea product that did develop sediment during storage.

5. Kogya does not teach specifically using pectin lyase as the pectinase enzyme in the reaction.

6. Kuntz teaches that both tea and fruit juices contain insoluble solids that prevent the clarity of the beverages. Kuntz further teaches that in the case of fruit juice, the cell walls of fruits consist of pectin, among other compounds. Kuntz teaches that adding pectin lyase enzymes to break down these pectin structures make it possible to extract a larger amount of juice and to produce a clear juice (Page 3, Paragraph 12).

7. Kuntz further teaches that enzymes used in fruit juice processing have a lower pH optima and have to be acid-tolerant since most juices have a pH between 3 and 4

(Page 5, Paragraph 6). Kogya teaches that the optimum pH of the enzymatic tea clarification reaction is at pH 3-8, and so one of ordinary skill in the art would have reasonably expected that pectin lyase would also be suitable for clarifying tea in view of the overlapping pH ranges of tea and most juices as well as the fact that both beverages contain pectin.

8. Kogya in view of Kuntz do not specifically state the presence of pectin in tea.

9. Tsai teaches a method of clarifying tea with enzymes including pectinases (Column 2, lines 20-25). Tsai further teaches that pectin, among other compounds, are constituents of tea cell-walls and that pectinases are cell-wall-digesting enzymes that break down one or more tea cell-wall constituents into simpler materials, a process which reduces the structural integrity and increases the permeability of the cell wall (Column 3, lines 1-10).

10. Therefore, it would have been obvious to one of ordinary skill in the art at the time that the invention was made for the pectinase used in the experiment taught by Kogya, to be pectin lyase, because Kogya teaches using a pectinase enzyme to clarify tea, and both Kuntz and Tsai teach that fruit juice and tea suffer from a similar problem of needing clarification and teach clarifying with enzymes that break down pectin in order to produce a clear product. In this light, one of ordinary skill would have been motivated to look to the fruit juice industry to solve this problem, particularly since Kuntz teaches that pectin lyase is a type of pectinase that has been found to successfully clarify fruit juice (Page 4, Paragraph 4).

11. Regarding amended Claim 7, Kogya in view of Kuntz and Tsai teach that the combination of the tea extract and pectinase is then mixed and allowed to stand (see Kogya, Page 2, Paragraph 7) and the sediment is then separated by centrifugation and the amount of sediment measured (see Kogya, Page 2, Paragraph 7). However, Kogya in view of Kuntz and Tsai do not specifically teach cooling the pectin lyase–treated tea extract to 0°C to 5°C (32-41°F).

12. Agbo teaches methods for producing a tea beverage which forms little or no haze when stored at refrigeration temperatures and to tea extracts so produced (Column 1, lines 9-11). Agbo teaches that conventional methods of removing insoluble tea solids are known as decreaming processes and utilize adjustments in process variables, such as temperature, to cause precipitation of the insoluble tea solids, followed by centrifugation or other equivalent techniques to remove precipitate complexes (Column 1, lines 25-30). Agbo teaches subjecting a tea extract to conventional decreaming steps which include chilling the tea extract to precipitate insoluble tea solids or tea cream and then utilizing separation equipment, such as centrifugation, to remove the solids and teaches in a preferred decreaming process, the tea extract is passed into a chill tank where the tea extract is cooled to a temperature of about 45°F, preferably in the range of about 33-40°F to cause precipitation of the insoluble tea solids or tea creams (Column 4, lines 4-11 and 15-18). It is noted that, like Agbo, Applicant states that the cooling of the extract is done to accelerate precipitation of the solids (see instant specification Page 4, lines 28-29).

13. Therefore, it would have been obvious to one of ordinary skill in the art at the time that the invention was made, for the method of Kogya in view of Kuntz and Tsai to have supplemented the centrifugation separation with a cooling step to the claimed temperature range because Agbo teaches that conventional methods of removing insoluble tea solids include reducing temperature followed by centrifugation or other techniques to remove precipitate complexes. Therefore, one of ordinary skill in the art would have been motivated by Agbo to combine a cooling step to the claimed temperature range with the centrifugation taught by Kogya in view of Kuntz and Tsai as an effective and conventional method of removing and separating insoluble tea solids in order to prepare tea beverages with reduced or no haze for consumers.

14. Claims 13-15, 21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kogya (CN 87103320 A) in view of Kuntz (Food Product Design, 1996), Tsai (U.S. Patent No. 4, 639375), and Agbo et al. (U.S. Patent No. 5,445,836), and further in view of Bida (Advance in Bioengineering), in light of Encyclopedia of Food Microbiology (2000).

15. Kogya in view of Kuntz, Tsai and Agbo are relied upon as above in the rejection of Claim 7.

16. Kogya in view of Kuntz, Tsai and Agbo do not specifically teach the pectin lyase being a microbial or fungal pectin lyase, or that the fungal pectin lyase is derived from Ascomycotina.

17. Regarding Claims 13 and 23, Bida teaches that the fungal enzymes that break down pectic substances are mainly polygalacturonase and pectin lyase (Page 1, Paragraph 3). Regarding Claims 14 and 15, Bida further teaches that pectin lyase is produced mainly by *Aspergillus* and also by *Saccharomyces cerevisia,* and other organisms, and that pectin lyase has been cloned from *Aspergillus niger* (Page 4, Paragraphs 5-6). In light of the evidentiary reference, Encyclopedia of Food Microbiology, that discloses that Saccharomyces cerevisia belongs to the family Saccharomycetaceae in Ascomycotina (see evidentiary reference, Encyclopedia of Food Microbiology, Page 2335, Column 2, Paragraphs 4 and 5), Bida teaches that the fungal pectin lyase is derived from Ascomycotina. Furthermore, it is commonly known that Aspergillus also falls under the subdivision of Ascomycotina, therefore, Bida teaches the claimed limitation for that reason as well. There does not appear to be a patentable distinction between a fungal pectin lyase derived from *Aspergillus* or from Ascomycotina since Aspergillus falls under the subdivision of Ascomycotina.

18. Regarding newly added Claim 21, Bida's teaching of a pectin lyase that is derived from a fungal source also reads on a microbial pectin lyase.

19. Therefore, it would have been obvious to one of ordinary skill in the art at the time that the invention was made for the pectin lyase taught by Kogya in view of Kuntz, Tsai and Agbo to be of a microbial or fungal origin and to be derived from *Aspergillus niger or* Ascomycotina because Bida teaches that both fungi are known sources of pectin lyase and that pectin lyase has also been cloned from *Aspergillus niger*. Therefore, one of ordinary skill in the art would have been motivated by Bida to identify

the above fungal sources as being reliable and available choices as sources of the enzyme for commercial processing.

20. Claims 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kogya (CN 87103320 A) in view of Kuntz (Food Product Design, 1996), Tsai (U.S. Patent No. 4, 639375), and Agbo et al. (U.S. Patent No. 5,445,836), and further in view of Sanderson (U.S. Patent No. 3, 787, 582).

21. Kogya in view of Kuntz, Tsai and Agbo are relied upon as above in the rejection of Claim 7.

22. Regarding Claims 16-19, Kogya in view of Kuntz, Tsai and Agbo do not teach the specific ranges as claimed of pectin lyase: from 0.1 to 1,000,000 UPTE per liter of the tea extract, from 1 to 100,000 UPTE per liter, from 10 to 10,000 UPTE per liter, and from 1,000 to 8,000 UPTE per liter.

23. Sanderson teaches using pectinase for preparing high bulk density tea powder with improved clarity (Column 1, Lines 21-26) and teaches that the percent of the pectinase enzyme preparation that is added to the tea extract is critical in view of the fact that too little unduly prolongs the reaction, while the use of excessive amount creates a haze problem of its own.

24. Therefore, it would have been obvious to one of ordinary skill in the art at the time that the invention was made, to optimize the concentration of pectin lyase enzyme in a method of reducing haze formation, because Sanderson teaches that the amount of pectinase enzyme added is critical in view of the fact that too little unduly prolongs the

reaction, while an excess create a haze problem of its own. It is within the skill of one of ordinary skill in the art to determine the optimum amount of pectin lyase used, in the absence of a showing of criticality in the claimed concentration of the pectin lyase enzyme. Furthermore, one of ordinary skill in the art would have been motivated by Sanderson to optimize the concentration of the pectin lyase enzyme in order to ensure that the clarification of the tea is successful for long-term storage of the tea product in a commercial setting.

25. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kogya (CN 87103320 A) in view of Kuntz (Food Product Design, 1996), Tsai (U.S. Patent No. 4, 639375), and Agbo et al. (U.S. Patent No. 5,445,836), and further in view of Alkorta (Enzyme and Microbial Technology).

26. Kogya in view of Kuntz, Tsai and Agbo are relied upon as above for the rejection of Claim 7.

27. Kogya in view of Kuntz, Tsai and Agbo do not teach the immobilization of the pectin lyase on a solid support.

28. Alkorta teaches clarifying fruit juice using a pectin lyase enzyme immobilized to Nylon (See Abstract of article). Alkorta teaches that the immobilization of pectic enzymes such as pectin lyase appear to offer several advantages in comparison with processes where soluble enzymes are used for the clarification of fruit juices (Column 2, Paragraph 2). In particular, Alkorta teaches that the immobilized pectin lyase was more stable at lower pH's than the soluble enzyme, that it caused a marked increase in the

thermal stability of the enzyme, that it showed extraordinary stability during storage at 4 °C, and, lastly, that no loss of activity was observed when the immobilized enzyme was used for 12 consecutive cycles of operation (See abstract of article).

29. It would have been obvious to one of ordinary skill in the art at the time that the invention was made to modify the pectin lyase taught by Kogya in view of Kuntz, Tsai and Agbo into an immobilized pectin lyase, as taught by Alkorta, in order to increase the economization and productivity of the enzymatic clarification of the tea. One of ordinary skill in the art would have been motivated to use immobilized pectin lyase in order to maximize the use of the enzyme with multiple batches of tea. Furthermore, because the immobilization increases the thermal stability of the enzyme, it would be possible for the clarification reaction to occur at a higher temperature, and thus at a faster rate.

30. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kogya (CN 87103320 A) in view of Kuntz (Food Product Design, 1996), Tsai (U.S. Patent No. 4, 639375), Agbo et al. (U.S. Patent No. 5,445,836), Bida (Advance in Bioengineering), and further in view of Xu (U.S. Patent Application No. 2002/0004085), and in light of Liu et al. (U.S. Patent No. 6,544,297).

31. Kogya in view of Kuntz, Tsai, Agbo and Bida are relied upon as above for the rejection of Claim 13.

32. Kogya in view of Kuntz, Tsai, Agbo and Bida do not specifically teach that the fungal pectin lyase is derived from Basidiomycotina.

33. Xu teaches a method of treating a food product with exogeneous enzymes such as pectinases, and that pectinases are defined as any enzymes that degrade pectic substances and teaches that pectinases include pectin lyase (Pages 2 and 3, Paragraph 45). Xu further teaches that in a more preferred embodiment the pectinase of the invention is a pectin lyase (Page 3, Paragraph 68), and further teaches that the source of the enzyme is not critical, that it can be of fungal or bacterial origin (Page 3, Paragraph 74), and that in a preferred embodiment, the enzymes are obtained from a fungal source such as from a filamentous fungal strain such as Phanerochaete (Page 4, Paragraph 77). In light of the evidentiary reference Liu that discloses that Phanerochaete is classified within the class Basidiomycetes, and within the subdivision of Basidiomycotina (see evidentiary reference Liu, Column 8, lines 12-14), Xu teaches that the fungal pectin lyase is derived from Basidiomycotina.

34. Therefore, it would have been obvious to one of ordinary skill in the art at the time that the invention was made for the pectin lyase taught by Kogya in view of Kuntz, Tsai, Agbo and Bida to be derived from Basidiomycotina because Xu teaches that Basidiomycotina is a known source of pectin lyase and one of ordinary skill in the art would have been motivated to identify Basidiomycotina as being a reliable and available choice as a source of the enzyme for commercial processing. Furthermore, it is noted that the use of another fungal source for pectin lyase would have been obvious to one of ordinary skill in the art and would not provide a patentable distinction for the claimed method from the other known fungal enzymes, in light of Applicant's disclosure that

states that a variety of sources can be used for the fungal pectin lyase in the claimed method (see instant specification, Page 3, lines 1-5).

35. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kogya (CN 87103320 A) in view of Kuntz (Food Product Design, 1996), Tsai (U.S. Patent No. 4639375) and Agbo et al. (U.S. Patent No. 5,445,836), and further in view of Klahorst (Food Product Design article, January 2003).

36. Kogya in view of Kuntz, Tsai and Agbo are relied upon as above for the rejection of Claim 7.

37. Kogya in view of Kuntz, Tsai and Agbo are taken as cited above in the rejection of Claim 7, but do not specifically teach that the pectin lyase is a pure pectin lyase free of the claimed side activities.

38. Klahort teaches that, when it comes to fruit processing, conventional wisdom dictated that the more types of pectinases added to fruit pulp, the better, because the action of the enzyme mixture would more thoroughly macerate the pulp and would enable the expression of more juice in the pressure and would provide plenty of time to eliminate the pectin (Page 3, Paragraph 3). Klahort further teaches that the additional activities acted synergistically to disassemble a wide variety of molecules, which resulted in the release of soluble polymers into the juice and filtering of the juice would remove the solids and colloids to recover a clarified juice (Page 3, Paragraph 3). Klahort teaches that it became apparent that overuse of the enzyme mixtures could cause its own problems, and that the enzyme mixtures liberally released other degraded

polymers and fibers which resulted in such problems as unexpected haze that developed in storage (Page 3, Paragraphs 4 and 5).

39. Klahort further teaches that eventually conventional wisdom gave way to new technologies, and that fruit processors discovered that more enzymatic breakdown is not necessarily more productive in term of quality and yield of clarified juice (Page 3, Paragraph 6). Klahort teaches that one advantage of new enzyme technology is the availability of monocomponent enzymes of higher purity and strength (Page 4, Paragraph 1). Klahort further teaches of a pure pectin lyase that will deliver the required juice yields without degrading other fruit structures and is known for its high activity at low pH and higher temperatures (Page 4, Paragraph 1). Klahort further teaches that the pure pectin lyase only degrades the pectin and does not produce other degradation products which are a concern to fruit processors. Klahort teaches that "there is no point in adding activities that are not required when we can produce enzymes now that feature only the specific activity required for optimal yield in the juice recovery process." (Page 4, Paragraph 1). The pure pectin lyase taught by Klahort is deemed to meet the claim limitation of a pure pectin lyase free of any side activities, including those claimed.

40. The commonality between fruit juice and tea has previously been established in Claim 7, therefore, it is reasonably expected that the same issues and concerns pertaining to fruit juice clarification would be applicable to tea clarification as well, absent any evidence to the contrary.

41. Therefore, it would have been obvious to one of ordinary skill in the art at the time that the invention was made, for the method of reducing haze in tea, as taught by Kogya in view of Kuntz, Tsai and Agbo, to have further comprised using a pure pectin lyase free of the claimed side activities, because Klahort teaches that it is known that mixtures of enzymes are not necessarily more productive in terms of quality and yield of clarified product and sometimes result in the production of detrimental degradation products that can cause other quality problems. One of ordinary skill in the art would have been motivated by Klahort to use a pure pectin lyase in a method of reducing haze in tea in order to ensure that only the desired components are targeted in the clarification process and to ensure that the particular enzyme activity featured is chosen for optimal yield of the final beverage product. Furthermore, as previously mentioned, since tea and some fruit juices have overlapping pH values and both contain pectin that contributes to storage haze problems, one of ordinary skill in the art would have reasonably expected that pure pectin lyase would be suitable and beneficial for tea clarification processes as well as fruit juice clarification processes, absent any evidence to the contrary.

Response to Arguments

42. The claim objection and 112 2nd rejection set forth in the office action mailed on 11/04/2009 are withdrawn in light of Applicant's amendments.

43. Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection. It is the position of the Examiner

that amended Claim 1 is found obvious over the cited prior art. It is also noted that cooling tea extracts to remove sediment and solids is a known and conventionally used tool used to increase the removal of sediment in order to prepare clear tea products. Regarding amended Claim 24, the rejection made of record in the office action mailed on 11/04/2009 has been maintained in light of the fact that Applicant did not address the rejection in the arguments presented.

44. Therefore, in light of the above mentioned facts, the office action is made final and is deemed proper.

Conclusion

45. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

46. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

47. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jenna A. Watts whose telephone number is (571) 270-7368. The examiner can normally be reached on Monday-Friday 9am-5:00pm.

48. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

49. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. SAYALA/
Primary Examiner, Art Unit 1781

/Jenna A. Watts/
Examiner, Art Unit 1781
June 9, 2010